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Dated: August 18, 2004

Signature: Shawn P. Foley  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT X  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Warrell et al.

Application No.: 10/759,308

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### **REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley  
Shawn P. Foley  
Registration No.: 33,071  
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08/25/2004 GMDRDOF1-00000016-121095-10759308  
01 FC:1806 100.00 DA



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### INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account

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PTO/SB/08a/b (08-03)

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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/759,308
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT X

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA**	US-132,275-B1	10-15-1872	Gettings		
AB**	US-232,807	10-05-1886	Dennett		
AC**	US-3,700,498	10-24-1972	Kanazawa et al.		
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AF**	US-2002/0183385	12-05-2002	Ellison et al.		
AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong		
AH**	US-6,770,304	08-03-2004	Warrell et al.		
AI**	US-2003/0099719	05/2003	Warrell et al.		
AJ**	US-6,723,351	04-20-2004	Warrell et al.		
AK**	US-6,773,792	05-11-2004	Lu		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	JP-51-88620		03-08-1976		
BB	WO-95/01789		01-19-1995		
BC	CN-1133725		10-23-1996		
BD	CN-1131037		09-18-1996		
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BK	WO-94/02103		02-03-1994		
BL	FR-2 539 993		03-31-1994		
BM	DE-43 17 331		12-01-1994		
BN	WO-95/22336		08-24-1995		
BO	LV-11667		06-20-1997		
BP	WO-94/02108		02-03-1994		

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878				
CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.				

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/759,308
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				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT X

		A.M.A. 97(1):3-5, 1931
	CC	STEPHENS, et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", University of Rochester, pp. 1488-1502, 1936
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	CR	LEE et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988
	CS	LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988
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	CZ	"Xionghuang, Realgar", Chinese Pharmacopia (I), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995
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	CB1	ANDRE et al., "The PML and PML/RAR $\alpha$ . Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996
	CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991

Examiner Signature		Date Considered	
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<p>Substitute for form 1449A/B/PTO</p> <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;"><i>(Use as many sheets as necessary)</i></p>				<i>Complete if Known</i>	
				Application Number	10/759,308
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT X

	CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996 ©American Society of Hematology 1996	
	CE1	CHEN et al., "Use of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As <sub>2</sub> O <sub>3</sub> Exerts Dose-Dependent Dual Effects on APL Cells", Blood 89(9):3345-3353, 1997 ©The American Society of Hematology 1997	
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	CG1	DE THE "L'oxyde d'arsenic: apres l'acide retinoique, un nouveau traitement cible dela leucemie aigue promyelocyttaire" Medecine/Sciences, 13:867-71, 1997	
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	CP1	LU et al., "Study of Reaglar in the Treatment of Acute Promyelocytic Leukemia (APL)-a pilot clinical and laboratory study on 32 Patients", China-Korea Medical Conference '97, 1997	
	CQ1	MERVIS, "Ancient Remedy Performs New Tricks", Science 273:578, 1996	
	CR1	NEUBAUER, "Arsenic Cancer: A Review", Arsenical Cancer, Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
	CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol. Suppl. 13, p. 363-65, 1989	
	CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990	
	CU1	SCHENK, Handbook of Preparative Inorganic Chemistry, 1:603, G. Brauer, Ed., Academic Press, New York, 2.sup.nd Edition, 1963	
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	CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.	
	CZ1	WANG et al., "Studies on Chemically Preventing Leukemia", Ghung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989	
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Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT X

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
	CE2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 patients", J. Harbin Medical Univ. 29(3):243, 1995	
	CF2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology 17(2) 1996	
	CG2	ZHU et al., "Arsenic-induced PML Targeting Onto Nuclear Bodies: implications for the treatment of acute promyelocytic leukemia", Proc. Natl. Acad. Sci. 94:3978-3983, 1997, ©The National Academy of Sciences of the USA 1997	
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